REMARKS

1. Applicants hereby submit the following:

[ ] a paper copy of a "Sequence Listing", complying with §1.821(c), to be incorporated into the specification as directed above;

[XX] an amendment to the paper copy of the "Sequence Listing" submitted on July 22, 2004, the amendment being in the form of substitute sheets;

[XX] the Sequence Listing in computer readable form, complying with §1.821(e) and §1.824, including, if an amendment to the paper copy is submitted, all previously submitted data with the amendment incorporated therein;

[ ] a substitute computer readable form to replace one found to be damaged or unreadable.

[ ] The computer readable form in this application no. 09/... is identical with that filed on .... [date sequence was filed] in application no. 09/ , filed [filing date]. In accordance with 37 C.F.R. §1.821(e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].

[XX] 2. The description has been amended to comply with §1.821(d).

3. The undersigned attorney or agent hereby states as follows:

(a) this submission does not include new matter [§1.821(g)];

(b) the contents of the paper copy (as amended, if applicable) and the computer readable form of the Sequence Listing, are the same [§1.821(f) and §1.825(b)];

(c) if the paper copy has been amended, the amendment is supported by the specification and does not include new matter [§1.825(a)]; and

(d) if the computer readable form submitted herewith is a substitute for a form found upon receipt by the PTO to be damaged or unreadable, that the substitute data is identical to that originally filed [§1.825(d)].

4. Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally

occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

The Examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

5. The STIC Raw Sequence Listing Error Report attached to the NDR stated the following:

(1) "Artificial" is an incomplete response in the <213> (Organism) field; the valid response is "Artificial Sequence".

(2) For each artificial sequence, the source of the genetic material must be identified in the <223> field; the identifications for sequences 1, 2, 3, and 11 were deemed incomplete; those for sequences 5-10 were apparently considered acceptable.

5.1. We have changed "Artificial" to "Artificial

Sequence" in all <213> fields.

5.2. While, for the reasons stated below, we don't think the requirement concerning the <223> field is proper, we have nonetheless amended the <223> fields for sequences 1, 2, 3 and 11, as follows:

ID 1: 128H described in Cheng, et al. USP 5,646,126

ID 2: Synthesized peptide shown in Fig. 17 BP 1-148

ID 3: Synthesizable activating sequence, shown in Fig. 1

ID 11: synthesized peptide shown in Fig. 17, as intermediate

Note that SEQ ID NO:1, which is cited at page 8, line 16 is a prior art sequence which we have not duplicated. Hence, the <223> field for ID 1 gives the prior art citation as the source.

With regard to ID3, this activating sequence is cited on page 26, line 34. While this sequence would most likely be prepared by direct synthesis, it could in theory be obtained by manipulation of human DNA. Hence we have characterized it as "synthesizable".

We also wish to point out that while the Examiner has accepted the characterization of each of sequences 6-9 as a "MUC1 fragment", of sequence 5 as a "MUC1 repeat consensus sequence", and of sequence 10 as a "MUC1 repeat", we do not mean to imply that these sequences were or must be obtained by fragmentation of MUC1, and indeed they are more likely to be prepared synthetically, cp BP1-148 in Fig. 17, and Exs. 27 and 28.

6. We believe that the PTO does not in fact have legal authority to require a further identification of "source", and

that inquiry into "source" is actually quite problematic. As I explained in my email of May 25 to Anne-Marie Corrigan:

(a) The authority for [the "source" requirement] is the preamble to the 1998 final rule. Unlike the final rule itself, which has force of law (if not contrary to statute, etc.), the preamble does not have any independent legal effect, i.e., it is simply an interpretation of the rule, and open to challenge.

(b) The preamble uses "should" language. The great weight of legal authority is that "should" is used to describe behavior which is encouraged but not required. In other words, even if the language of the preamble were part of the rule, it does not impose a legal obligation.

(c) The stated reason for the promulgation of the 1998 final rule was to conform US sequence listing requirements to ST.25. However, ST.25 does not appear to require that field <223> provide the "source" of an artificial sequence. See sections 30, 33-36; Appendix 1 entries for <213> and <223>.

(d) The application (10/502,085) is the national stage of a PCT application. PCT rules require sequence submissions in accordance with ST.25. Article 27(1) of the Treaty says "no national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations." (The only exception is when the national law is more favorable, see 2(4), which doesn't apply here.) It thus appears that even if the preamble language were worded as compulsory, and if it were in the rule, it would still be improper as contrary to Treaty requirements to apply it in any national stage application.

(e) The "requirement" of disclosure of source can readily come into conflict with the ban on adding new matter in a sequence listing. For example, suppose that a peptide was synthesized, but this is not explicitly stated anywhere in the specification. If so, then stating "synthesized peptide" in <223> would appear to violate 37 CFR 1.825(a). Moreover, since the sequence listing requirement is not intended to be or considered a substantive patent law requirement, cp. 1.821(i), the courts would frown on any interpretation of the rules which forced substantive analysis not explicitly required by the rule.

(f) It is not clear where the line is to be drawn vis-a-vis identification of source. Suppose, for example, that a sequence was extracted from a plasmid, call it pXYZ1. Is stating the source to be pXYZ1 good enough? Or does one then have to inquire into how pXYZ1 was constructed? What if the sequence was extracted from pXYZ1 and then modified--must one describe the modifications in the sequence listing?

Respectfully submitted,

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